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Pharmaceutical And Analytical Study Of Shunthyadi Churna: Quality Assessment And Standardization

Dr. Deepika Dilip Vyawahare[1]*, Dr. Virendra Baburao Pawar[2]
[1]PhD Scholar, Department of Kayachikitsa, Bharati Vidyapeeth (Deemed to be University), College of Ayurved and Hospital, Katraj, Pune, 411043, Maharashtra, India.
[1]Assistant Professor, Department of Kayachikitsa, ASPM Ayurved College, Hospital & Research Institute, Buldana, 443001, Maharashtra, India
[2]Associate Professor, Department of Kayachikitsa, Bharati Vidyapeeth (Deemed to be University), College of Ayurved and Hospital, Katraj, Pune, 411043, Maharashtra, India

Abstract: *Shunthyadi Churna is a classical Ayurvedic polyherbal powder formulation traditionally employed for digestive, respiratory, and inflammatory disorders. This study aimed to establish comprehensive quality standards through pharmaceutical and analytical evaluation. A batch prepared according to classical methodology was analyzed at Qualichem Laboratories, Nagpur (May 25–June 1, 2024). Physicochemical parameters included loss on drying (8.45% w/w), total ash (6.82% w/w), acid-insoluble ash (1.24% w/w), water-soluble extractive (18.76% w/w), alcohol-soluble extractive (12.43% w/w), and pH (5.12). Heavy metal content was within safe limits: lead (0.284 mg/kg), arsenic (0.142 mg/kg), mercury (0.098 mg/kg), cadmium (<0.1 mg/kg). Total phenolic content measured 1.24% w/w (gallic acid equivalent). Aflatoxins were below detection limits. Microbiological analysis revealed total bacterial count of 180 cfu/g, yeast and mold <10 cfu/g, with absence of pathogens including Escherichia coli, Salmonella, Staphylococcus aureus, and Pseudomonas aeruginosa. High-Performance Thin-Layer Chromatography (HPTLC) established characteristic fingerprints with eight peaks at 254 nm and five fluorescent zones at 366 nm, confirming chemical consistency. These comprehensive findings validate Shunthyadi Churna as a safe, standardized formulation conforming to Ayurvedic Pharmacopoeia requirements, suitable for therapeutic applications and warranting further pharmacological investigation.*
Keywords: *Shunthyadi Churna, Ayurveda, HPTLC fingerprinting, quality control, herbal standardization, physicochemical analysis*

INTRODUCTION:

Ayurveda, the traditional Indian system of medicine, relies extensively on polyherbal formulations for managing diverse health conditions [1]. Shunthyadi Churna represents a classical powder preparation comprising four principal herbs: Shunthi (Zingiber officinale), Musta (Cyperus rotundus), Ativisha (Aconitum heterophyllum), and Guduchi (Tinospora cordifolia), traditionally indicated for digestive disorders, respiratory complaints, and inflammatory conditions [2]. The formulation operates through synergistic mechanisms including digestive stimulation and astringent actions [3].

Individual constituents possess well-documented pharmacological properties. Shunthi exhibits carminative and anti-inflammatory effects [4], Musta demonstrates digestive and antimicrobial activities [5], Ativisha provides antipyretic benefits [6], while Guduchi offers immunomodulatory properties [7]. Despite traditional efficacy, the increasing global acceptance of herbal medicines necessitates rigorous quality control and standardization [8].

Contamination with heavy metals, microbial pathogens, or mycotoxins poses significant safety risks [9,10]. Regulatory authorities including WHO and API mandate comprehensive quality assessment [11]. This study establishes physicochemical parameters, chemical safety profiles, microbiological purity, and HPTLC fingerprints to validate quality and batch consistency.

MATERIALS AND METHODS

Sample Preparation

Shunthyadi Churna was prepared following classical Ayurvedic methodology [12]. Authenticated raw materials were procured, cleaned, dried, and individually powdered through mesh #80, then mixed in equal

proportions (1:1:1:1 w/w). The final powder was sieved through mesh #85 and stored in moisture-proof containers at room temperature.

Table 1: Composition of Shunthyadi Churna

Ingredient	Latin Name	Family	Part Used	Ratio
Shunthi	Zingiber officinale	Zingiberaceae	Dried Rhizome	1
Musta	Cyperus rotundus	Cyperaceae	Rhizome	1
Ativisha	Aconitum heterophyllum	Ranunculaceae	Roots	1
Guduchi	Tinospora cordifolia	Menispermaceae	Stem	1

Analytical Facility

Analysis was conducted at Qualichem Laboratories, Nagpur (ISO 9001:2015 certified) from May 25 to June 1, 2024, following API protocols.

Physicochemical Analysis

Loss on Drying (LOD): Determined by heating at 105°C until constant weight (API method) [13].

Total Ash and Acid-Insoluble Ash: Measured by incineration at 450°C and subsequent acid treatment (API method) [13].

Extractive Values: Determined by maceration with water and ethanol, followed by gravimetric measurement (API method) [13].

pH: Measured in 1% aqueous solution using calibrated pH meter (API method) [13].

Particle Size Distribution: Determined using standard sieve analysis.

Chemical Analysis

Heavy Metals: Lead, arsenic, mercury, and cadmium were quantified using atomic absorption spectrophotometry (method STP/0046-I, LLQ: 0.1 mg/kg) [14].

Total Phenolic Content: Determined spectrophotometrically using Folin-Ciocalteu reagent, expressed as gallic acid equivalent (API method) [13].

Aflatoxin Analysis: Aflatoxins B1, B2, G1, and G2 were analyzed using HPLC with fluorescence detection (detection limit: 0.001 ppm) [15].

Microbiological Assessment

Total bacterial count and yeast/mold count were determined using standard plate count methods. Pathogen screening included specific tests for Escherichia coli, Salmonella species, Staphylococcus aureus, and Pseudomonas aeruginosa using selective culture media (API methods) [13].

HPTLC Fingerprinting

Analysis was performed using CAMAG TLC Scanner. Sample (2 g) was extracted with methanol (20 ml) by sonication, filtered, and concentrated.

Chromatographic Conditions: Silica gel 60 F_{254} plates, mobile phase Toluene:Ethyl Acetate:Formic Acid (5:4:0.2 v/v/v), development to 70 mm, detection at 254 nm and 366 nm, data analysis using winCATS software.

RESULTS:

Organoleptic Characteristics

Shunthyadi Churna exhibited light brown to yellowish-brown color, characteristic aromatic pungent odor, pungent-bitter taste, and fine to moderately coarse texture as a free-flowing homogeneous powder.

Physicochemical Parameters

Table 2: Physicochemical Analysis Results

Parameter	Result	API Limit	Compliance
Loss on Drying	8.45% w/w	NMT 10%	✓
Total Ash	6.82% w/w	NMT 10%	✓
Acid-Insoluble Ash	1.24% w/w	NMT 2%	✓
Water-Soluble Extractive	18.76% w/w	NLT 12%	✓
Alcohol-Soluble Extractive	12.43% w/w	NLT 8%	✓
pH (1% Solution)	5.12	4.5–6.5	✓

NMT: Not More Than; NLT: Not Less Than

Particle size analysis revealed 75.4% particles within 180–355 µm range, indicating optimal fineness for oral administration and dissolution.

Chemical Safety Assessment

Table 3: Heavy Metal Analysis

Heavy Metal	Result (mg/kg)	API/WHO Limit	Compliance
Lead (Pb)	0.284	≤10	✓
Arsenic (As)	0.142	≤3	✓
Mercury (Hg)	0.098	≤1	✓
Cadmium (Cd)	<0.1 (BQL)	≤0.3	✓

BQL: Below Quantification Limit

Total phenolic content measured 1.24% w/w (gallic acid equivalent), indicating presence of bioactive antioxidant compounds. Aflatoxins (B1, B2, G1, G2) were below detection limit (<0.001 ppm), confirming absence of mycotoxin contamination.

Microbiological Safety

Table 4: Microbiological Analysis

Parameter	Result	API Limit	Status
Total Bacterial Count	180 cfu/g	$\leq 10^5$ cfu/g	Complies
Yeast and Mold Count	<10 cfu/g	$\leq 10^3$ cfu/g	Complies
Escherichia coli	Absent	Absent	Complies
Salmonella spp.	Absent	Absent	Complies
Staphylococcus aureus	Absent	Absent	Complies
Pseudomonas aeruginosa	Absent	Absent	Complies

HPTLC Fingerprinting

Table 5: HPTLC Peak Data at 254 nm

Peak	Track 2 Rf	Height (AU)	Area (%)	Track 3 Rf	Height (AU)	Area (%)
1	0.02	726.5	72.88	0.04	725.3	74.02
2	0.27	24.0	2.74	0.27	24.7	3.02
3	0.41	28.2	4.33	0.41	25.7	3.58
4	0.59	43.6	5.52	0.49	24.7	2.78
5	0.62	58.1	6.89	0.59	37.6	3.61
6	0.73	23.2	2.85	0.63	51.1	6.62
7	0.80	17.3	1.76	0.74	20.4	3.07
8	1.03	34.4	3.03	1.02	34.1	3.29

Table 6: HPTLC Peak Data at 366 nm (Fluorescence)

Peak	Track 2 Rf	Height (AU)	Area (%)	Track 3 Rf	Height (AU)	Area (%)
1	0.02	734.6	72.90	0.04	736.6	75.36
2	0.27	25.6	3.76	0.27	28.3	4.40
3	0.50	21.4	2.85	0.49	40.7	3.97
4	0.60	37.6	5.89	0.60	37.2	6.30
5	0.73	48.5	8.51	0.73	50.6	9.96

HPTLC analysis revealed eight distinct peaks at 254 nm and five major fluorescent zones at 366 nm. The dominant peak at Rf 0.02–0.04 (72–75% of total area) likely represents polar glycosides or phenolic compounds. Excellent concordance between duplicate tracks confirmed batch homogeneity. Visual inspection showed consistent banding patterns with intense fluorescence at Rf ~0.02 and moderate fluorescence at Rf ~0.73 under 366 nm illumination.

DISCUSSION:

This comprehensive analytical study establishes Shunthyadi Churna as a high-quality, safe Ayurvedic formulation meeting international standards. The physicochemical parameters demonstrate excellent manufacturing controls. Loss on drying (8.45% w/w) ensures microbial stability while preventing excessive brittleness [16]. Total ash (6.82% w/w) and acid-insoluble ash (1.24% w/w) confirm minimal contamination, indicating proper cleaning of raw materials [17]. High extractive values water-soluble (18.76% w/w) and alcohol-soluble (12.43% w/w) reflect rich phytochemical content, advantageous for traditional water-based administration [18]. The slightly acidic pH (5.12) provides gastric compatibility and antimicrobial stability [19].

Heavy metal analysis revealed levels substantially below regulatory limits, eliminating toxicity concerns. Lead (0.284 mg/kg), arsenic (0.142 mg/kg), mercury (0.098 mg/kg), and cadmium (<0.1 mg/kg) demonstrate adherence to Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP) [20,21]. The absence of aflatoxins (<0.001 ppm) confirms proper drying, storage, and absence of fungal contamination [22].

Total phenolic content (1.24% w/w) represents bioactive constituents responsible for antioxidant, anti-inflammatory, and antimicrobial properties [23]. These phenolics derive from gingerols in Shunthi, flavonoids in Guduchi and Musta, and phenolic alkaloids in Ativisha [24,25]. The moderate phenolic level is appropriate for this formulation's diverse phytochemical composition [26].

Microbiological assessment confirmed excellent hygiene standards with low bacterial count (180 cfu/g) and minimal fungal contamination (<10 cfu/g) [27]. The absence of pathogens validates manufacturing sanitation and personnel hygiene [28]. Microbial stability can be attributed to low moisture content and inherent antimicrobial properties of ingredients [29].

HPTLC fingerprinting established characteristic chemical profiles serving multiple quality control functions. The reproducible peak patterns at 254 nm and 366 nm provide identity verification, batch consistency confirmation, quality assessment, adulteration detection, and stability monitoring capability [30,31]. The dominant peak at Rf 0.02–0.04 showing both UV absorption and fluorescence suggests major aromatic constituents, likely flavonoid glycosides from Guduchi [32]. Mid-range peaks represent moderately polar compounds including alkaloids and phenolic acids, while the peak at Rf ~1.03 indicates non-polar constituents such as volatile oils.

Comparison with Shunthyadi Kwath reveals dosage form-dependent differences. The churna formulation exhibits lower moisture content, significantly higher phenolic concentration, and enhanced storage stability while maintaining comparable safety profiles [33]. Future investigations should include multi-batch validation, marker-based standardization through HPLC, stability studies, and clinical trials to correlate analytical profiles with therapeutic outcomes [34,35].

CONCLUSION:

This comprehensive pharmaceutical and analytical study validates Shunthyadi Churna as a safe, high-quality, standardized Ayurvedic formulation. All physicochemical parameters comply with API specifications. Heavy metal content remains substantially below safety limits, with aflatoxins undetectable. Microbiological analysis confirms excellent hygiene with pathogen absence. HPTLC fingerprinting establishes characteristic chemical profiles providing validated identity markers for quality control. These findings establish Shunthyadi Churna's conformity to international pharmaceutical standards, supporting its integration into evidence-based healthcare systems and providing a robust framework for routine quality control and regulatory compliance.

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Conflict Of Interest

The authors declare no conflicts of interest.

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